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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/148,973	09/04/1998	J.TIMOTHY GREENAMYRE	PC10023A	4263

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EXAMINER	
GARCIA, MAURIE E	
ART UNIT	**PAPER NUMBER**
1627	29

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applica...(s)
09/148,973	Greenamyre et al
Examiner	**Art Unit**
Maurie E. Garcia, Ph. D.	1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *THREE* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 18, 2002*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-8* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-3 and 5-7* is/are rejected.

7) ☒ Claim(s) *4 and 8* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Please note the change in examiner.

1. The Response filed January 18, 2002 (Paper No. 28) is acknowledged. No claims were amended, added or cancelled. Therefore, claims 1-8 are pending and are examined on the merits in this action.

Withdrawn Rejections

2. All previous rejections are withdrawn in view of applicant's amendments and arguments. New rejections are set forth below. Since these rejections are not necessitated by any amendment by applicant, this case remains in non-final status.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were

made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold et al (US 5,670,516; of record) in view of Adams et al (Principles of Neurology; on PTO-1449).

Arnold et al teach a number of neurological disorders such as "drug-induced Parkinson's Disease" and other neurological conditions such as "muscular spasms" and "tardive dyskinesia" (see column 1, line 55 through column 2, line 4). The reference teaches that the "use of a neuroprotective agent, such as an AMPA receptor antagonist, is believed to be useful in treating these disorders" (column 2, lines 4-9). Arnold et al lacks the specific teaching of using an AMPA receptor antagonist to "treat dyskinesia associated with dopamine agonist therapy".

However, it was well known in the art at the time of filing that dyskinesia is a side effect associated with dopamine agonist therapy. For example, Adams et al when discussing L-dopa treatment of Parkinson's Disease states that one of the "most common and troublesome effects of L-dopa" is dyskinesia (see page 1073, 1st column, 2nd full paragraph). Furthermore, Adams et al teach the combination

of L-dopa with a decarboxylase inhibitor (carbidopa or benserazide) which is standard L-dopa therapy and reads on the limitations of the instant claims 2, 3, 6 and 7. See page 1072 of Adams et al, 2nd column, 3rd paragraph.

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use an AMPA receptor antagonist (as taught by Arnold et al) to treat dyskinesia associated with dopamine agonist therapy for the following reasons. Adams et al teach that one of the "most common and troublesome effects of L-dopa" is dyskinesia. Arnold et al teaches a number of neurological disorders such as "drug-induced Parkinson's Disease" and other neurological conditions such as "muscular spasms" and "tardive dyskinesia" that can be treated using an AMPA receptor antagonist. Thus, one of ordinary skill would be motivated to use an AMPA receptor antagonist to treat dyskinesia associated with dopamine agonist therapy because Arnold et al teach that blocking AMPA receptors is an effective way to treat neurological disorders, such as dyskinesias and Adams et al teach that one of the "most common and troublesome effects of L-dopa" is dyskinesia.

6. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stella et al (Annals of Neurology, 1996; of record) in view of Arnold et al (US 5,670,516; of record) and further in view of Adams et al (Principles of Neurology; on PTO-1449).

Stella et al teach that antagonists of the NMDA receptor "reverse levodopa-induced motor fluctuations in animal models of Parkinson's disease" (see Abstract). The reference teaches administering the standard therapy for Parkinson's disease, i.e. combination of L-dopa with a decarboxylase inhibitor (benserazide) and that this induced "moderately severe dyskinesias" (page 575, 1st column under 'Drug Administration'). Stella et al teach that administration of an antagonist of the NMDA receptor "substantially reduced" or "abolished" certain dyskinesias resulting from L-dopa therapy, thus providing "an ameliorative effect on levodopa-induced dyskinesias" (see page 577, 1st column under 'Discussion'). Stella et al lack the teaching of using an AMPA receptor antagonist.

However, Arnold et al teach a number of neurological disorders such as "drug-induced Parkinson's Disease" and other neurological conditions such as "muscular spasms" and "tardive dyskinesia" (see column 1, line 55 through column 2, line 4). The reference teaches that the "use of a neuroprotective agent, such as an AMPA receptor antagonist, is believed to be useful in treating these disorders" (column 2, lines 4-9). Arnold et al teach that NMDA and AMPA receptors are subtypes of the same receptor (see column 1, lines 25-33).

Also, it was well known in the art at the time of filing that dyskinesia is a side effect associated with dopamine agonist therapy. For example, Adams et al when discussing L-dopa treatment of Parkinson's Disease states that one of the "most common and troublesome effects of L-dopa" is dyskinesia (see page 1073, 1st column, 2nd full paragraph). Furthermore, Adams et al teach the combination

of L-dopa with a decarboxylase inhibitor (carbidopa or benserazide) which is standard L-dopa therapy and reads on the limitations of the instant claims 2, 3, 6 and 7. See page 1072 of Adams et al, 2nd column, 3rd paragraph.

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use an AMPA receptor antagonist (as taught by Arnold et al) in the method of Stella et al to treat dyskinesia associated with dopamine agonist therapy for the following reasons. Adams et al teach that one of the "most common and troublesome effects of L-dopa" is dyskinesia. Stella et al specifically teach that antagonists of the NMDA receptor produce "an ameliorative effect on levodopa-induced dyskinesias". Arnold et al teaches a number of neurological disorders such as "drug-induced Parkinson's Disease" and other neurological conditions such as "muscular spasms" and "tardive dyskinesia" that can be treated using an AMPA receptor antagonist. Thus, one of ordinary skill would be motivated to use an AMPA receptor antagonist to treat dyskinesia associated with dopamine agonist therapy because Arnold et al teach that blocking AMPA receptors is an effective way to treat neurological disorders, such as dyskinesias and Adams et al teach that one of the "most common and troublesome effects of L-dopa" is dyskinesia. Furthermore, since Stella et al teach that antagonists of the NMDA receptor produce "an ameliorative effect on levodopa-induced dyskinesias" and Arnold et al teach that NMDA and AMPA receptors are subtypes of the *same receptor* then it would be obvious to one of

ordinary skill to substitute an antagonist of the AMPA receptor for the antagonist of the NMDA receptor taught by Stella et al.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

8. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,136,812.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following:

The claims of the U.S. '812 patent and the instant application are directed to methods for treating dyskinesias associated with agonist therapy in a mammal, which comprises administering to said mammal a compound which is an antagonist of the AMPA receptor.

The U.S. '812 patent is directed to a method for treating dyskinesias associated with agonist therapy in a mammal, which comprises administering to said mammal a compound as defined therein by the specific chemical compounds in claims 1-10. These compounds are antagonists of the AMPA receptor. The instant application is directed generally to a method for treating dyskinesias associated with agonist therapy in a mammal, which comprises administering to said mammal a compound which is a antagonist of the AMPA receptor.

In view of the above, the instant claims differ from the U.S. '812 patent in that they do not specifically claim the use of the specific compound species administered in the methods of the U.S. '812 patent. However, the subject matter claimed in the instant application would be obvious to one of ordinary skill in view of the claims of U.S. '812 patent because the claims set forth a method for treating dyskinesias associated with agonist therapy in a mammal, which comprises administering to said mammal a compound which is a antagonist of the AMPA receptor.

Response to Arguments

10. Applicant's arguments filed January 18, 2002 have been fully considered but are moot in view of the new ground(s) of rejection set forth in this action. Also, Applicant has stated that they are deferring the filing of a Terminal Disclaimer until the claims are otherwise indicated as allowable. Thus the Double Patenting rejection is maintained for reasons of record.

Status of Claims/Conclusion

11. No claims are allowed. However, claims 4 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims {subject to the filing of a terminal disclaimer over US 6,136,812 as set forth above}.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:00 to 6:30 and alternate Fridays.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.
April 22, 2002

MAURIE E. GARCIA, PH.D
PATENT EXAMINER

UNITED STATES PATENT AND TRADEMARK OFFICE

Facsimile Transmission

Date: August 27, 2002

To: Kristina Konstas

Phone: Voice 212 733-6380 **Fax** 212 573-1939

From: Exr. Maurie Garcia Baker

Phone: Voice 703-308-0065 **Fax** 703-308-4242

Pages, including coversheet: 12

Serial number: 09/148,973

Notes: Courtesy copy of Office Action as requested by Ms. Konstas

Exr. Maurie Garcia Baker